REMARKS

I. Status of the Claims

Claims 1 through 28 have been cancelled herein. Claims 29 through 77 are new. Support for each of the new claims can be found in the specification and claims as originally filed. Accordingly, Applicants submit that the claims presented herein raise no issue of new matter. Applicants respectfully request their consideration in view of the remarks herein.

II. Claim Rejection under 35 U.S.C. § 112 First Paragraph

The Examiner has rejected claims 7 and 10 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Applicants respectfully disagree with this rejection for at least the following reasons. With respect to claim 10, the specification consistently describes a superelastic alloy as one embodiment, but not the only embodiment of the disclosed alloy. In fact, paragraph [00077] of the specification clearly describes an alternative embodiment as one that "may not have superelastic qualities." Thus, this rejection is improper and should be withdrawn. The cancellation of claim 7 has rendered this rejection moot, and Applicants therefore respectfully request its withdrawal.

III. Double Patenting Rejection in View of U.S. Application No. 09/752,212

The Examiner has rejected claims 1-4, 6, 8, 12-14, 17-22, and 24-28 under the judicially created doctrine of obviousness-type double patenting in view of U.S. Application No. 09/752,212. Office Action at 3. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

While Applicants have cancelled each of claims 1-4, 6, 8, 12-14, 17-22, and 24-28, thereby rendering the outstanding rejection moot, to the extent that the Examiner considers reapplying this rejection against the herein added claims, Applicants hereby inform the Examiner that U.S. Patent Application No. 09/752,212 issued on February 15, 2005, as U.S. Patent No. 6,855,161 to Boylan et al. (hereafter, "the Boylan patent"). As the Examiner will note, the claims of the Boylan patent are directed towards a method for providing a superelastic, radiopaque metallic stent for medical applications. Boylan, columns 11 and 12. The currently pending claims of the present application, however, are directed towards a product, namely a medical device, such as a stent, which is suitably used in a body lumen. Applicants respectfully submit that the present product claims are in a statutorily different class of invention than the method claims of the Boylan patent, and thus are patentable thereover.

IV. Claim Rejection Under 35 U.S.C. § 102(b) - Duerig et al.

The Examiner has rejected claims 1, 2, 5-14, 16-22, and 24-28 as allegedly anticipated under 35 U.S.C. 102(b) by EP 0 873 734 A2 to Duerig et al. (hereafter, "Duerig"). Office Action at 3-4. Applicants have cancelled claims 1, 2, 5-14, 16-22, and 24-28 herein. Therefore, Applicants respectfully submit that the rejection under 35 U.S.C. § 102(b) is moot, and its withdrawal is respectfully requested.

V. Claim Rejection Under 35 U.S.C. § 103(a) - Nagy in view of Avellanet

The Examiner has rejected claims 1, 4, 6, 7, 12, 14, 18, 20, 22, 24, and 25 as allegedly unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,210,312 to Nagy (hereafter, "Nagy) in view of U.S. Patent No. 6,137,060 to Avellanet (hereafter, "Avellanet"). Office Action at 4-5. Claims 1, 4, 6, 7, 12, 14, 18, 20, 22, 24, and 25 have

been cancelled herein. Therefore, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) is moot, and its withdrawal is respectfully requested.

VI. Remarks Regarding New Claims 29-77

With respect to new claims 29-77, Applicants respectfully submit the following remarks in an effort to clarify the distinctions between pending claims 29 to 77 and the previously cited prior art.

A. EP 0 873 734 A2 (Duerig)

To establish a *prima facie* case of anticipation or obviousness over a single prior art reference, the Examiner must establish that the prior art reference teaches or suggests all of the claim limitations. M.P.E.P. § 2143. Applicants submit that Duerig alone cannot meet this requirement with respect to present claims 29-77, and thus cannot anticipate or obviate these claims for at least the reasons that follow.

1. Claim 29 and its Dependents

Independent claim 29 recites "a medical device for use in a body lumen, comprising a tubular-shaped body having a wall defining a pattern of struts, wherein the tubular-shaped body comprises a NiTi alloy, said NiTi alloy further comprising at least one ternary element chosen from Pt and Pd." As Duerig fails to teach or suggest the inclusion of Pt or Pd, Applicants maintain that Duerig does not anticipate or render obvious claim 29 nor any of its dependents.

Duerig discloses stents making use of "an alloy which is capable of exhibiting a large hysteresis in a loading or an unloading cycle. This can be obtained by using certain nickel titanium based alloys, with ternary additions of at least one of niobium,

hafnium, tantalum, tungsten, and gold." Duerig, section [0005] and claim 1. Regarding the amount of the ternary element, Duerig discloses that "about 3 atomic percent... to about 20 atomic percent based on the weight of the alloy composition, of [the] at least one ternary element" may be used. *Id.* at section [0006] and claim 1. Duerig further discloses that "the alloy in the stent will be treated so as to provide appropriate elastic properties for the intended application." *Id.* at section [0013]. Duerig also discloses that,

> the treatment will generally involve a combination of thermal and mechanical treatment steps. Non-linear superelastic properties can be introduced...by a process which involves cold working the alloy for example by a process that involves pressing, swaging, or drawing. The cold working step is followed by an annealing step, which the component is restrained in the configuration... The technique for introducing superelastic properties can be varied from that described above. For example, the alloy could be deformed beyond a particular desired configuration and then heat treated such that there is a thermally induced change in configuration... An example of a treatment that can be applied... includes cold working the article by at least about 20%... The treatment generally includes an annealing step involving exposure to elevated temperature... The annealing temperature will preferably be at least about 300°C, more preferably at least about 550°C."

Id. at sections [0013]-[0015].

However, Duerig does not disclose ternary NiTi alloys where the ternary element is chosen from Pt and Pd, as presently claimed. Thus, because Duerig does not disclose each and every element of claim 29, Applicants submit that Duerig cannot anticipate claims 29 through 42 under 35 U.S.C. § 102.

2. Claim 43 and its Dependents

Independent Claim 43 recites "a medical device for use in a body lumen, comprising a tubular-shaped body having a wall defining a pattern of struts, wherein the

tubular-shaped body comprises a non-superelastic NiTi alloy, said alloy further comprising at least one ternary element chosen from iridium, platinum, gold, rhenium, tungsten, palladium, rhodium, tantalum, silver, ruthenium, hafnium, osmium, zirconium, niobium, and molybdenum." Applicants submit that because Duerig does not disclose the use of the recited non-superelastic alloys, it does not anticipate or render obvious claim 43 and its dependents.

Duerig's silence with respect to *non-superelastic* NiTi alloys containing a ternary element chosen from the group of elements recited in present claim 43 is consistent with the processing conditions described in this reference, which are known in the art to result in superelastic NiTi, i.e., thermal and mechanical treatment, more specifically cold working followed by annealing. Duerig, sections [0013]-[0018], and [0027]; *See also*, Duerig et al. "An Engineer's Perspective of Superelasticity," Engineering Aspects of Shape Memory Alloys at pages 369 and 382-392.[1] Applicants therefore maintain that Duerig does not teach nor suggest each and every element of claim 43 and its dependents. Thus this reference cannot anticipate or render obvious these claims under 35 U.S.C. §102(b) and/or §103.

The Examiner's attention is furthermore specifically directed to well-known Federal Circuit decisions holding that if a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See, *In re Fritch*, 972 F.2d 1260, 1265-66, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir.

[1] A copy of the relevant portions of this book accompany the information disclosure statement filed concurrently herewith.

1992); *In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959) (holding the suggested combination of references improper under section 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate."). For at least these reasons, claims 43 and its dependents would not be obvious in view of Duerig under 35 U.S.C. § 103(a).

3. Claim 53 and its Dependents

Claim 53 recites, "a medical device for use in a body lumen, comprising a tubular-shaped body having a wall defining a pattern of struts, wherein the tubular-shaped body comprises a superelastic NiTi alloy, said alloy further comprising at least one ternary element chosen from iridium, platinum, rhenium, palladium, rhodium, silver, ruthenium, osmium, zirconium, and molybdenum."

As noted above for claim 29, Duerig is completely silent with respect to ternary NiTi alloys containing a ternary element other than Nb, Hf, Ta, W, and Au. *See Duerig*, section [0005] and claim 1. Thus, as Duerig does not disclose each and every element of claim 53 and its dependents, Applicants submit that Duerig cannot anticipate claim 53 and its dependents under 35 U.S.C. § 102. Further, given that Duerig is silent with respect to other ternary elements, one of ordinary skill in the art would not have been motivated by the teachings of Duerig to modify such teachings so as to arrive the invention recited by claim 53 and its dependents, much less would the skilled artisan have had a reasonable expectation of success. Therefore, Applicants submit that Duerig does not render claim 53 and its dependents obvious under 35 U.S.C. § 103(a).

4. Claims 61 and 63, and their Dependents

Applicants respectfully submit that claims 61 and 63 contain the same distinguishing features as discussed above for claims 43 and 53, respectfully. Accordingly, claims 61 and 63 are neither anticipated nor rendered obvious by Duerig.

B. U.S. 6,210,312 to Nagy in combination with U.S. 6,137,060 to Avellanet

To establish a prima facie case of obviousness, the Examiner must show, at a minimum, that (1) the prior art references teach or suggest all of the claim limitations, and (2) there would have been a suggestion or motivation in the reference or in the knowledge generally available to one of ordinary skill in the art to modify the reference in order to recreate Applicants' claimed invention. *See* M.P.E.P. §§ 2143.01 and 2143.03. Applicants respectfully submit that there is no teaching in the disclosures of Nagy and/or Avellanet that would motivate one of ordinary skill in the art to combine these references with a reasonable expectation of success of obtaining the presently claimed invention.

1. Claim 29 and its Dependents

Independent claim 29 recites "A medical device for use in a body lumen, comprising a tubular-shaped body having a wall defining a pattern of struts, wherein the tubular-shaped body comprises a NiTi alloy, said NiTi alloy further comprising at least one ternary element chosen from Pt and Pd."

The Nagy patent discloses a guide wire formed from a superelastic NiTi alloy, wherein the alloy further contains up to 10% of additional alloying elements, such as Pt, Pd, W, V, Cu, and Be. Nagy, column 2, lines 28-37. Nagy does not disclose a medical

device comprising a wall defining a pattern of struts. While Nagy does disclose using radiopaque markers on the body or the end of the guidewire, "to allow the physician to see the position of the guidewire distal end [29] on a fluoroscope," (*id.* column 5, lines 37-40 and column 8, lines 40-45), it is completely silent with respect to the radiopacity and flexibility of a medical device formed from these ternary alloys. Thus, this reference does not teach the claimed invention.

Avellanet does not cure the identified deficiencies of Nagy. For example, this reference is directed towards extremely flexible wires which are suitable for use as medical guidewires or as wires of a medical stent. Avellanet, column 3, lines 1-3 (emphasis added). To this end, Avellanet discloses wires comprising, "two or more strands of a nickel-titanium alloy wire and a strand of high density wire such as gold, silver, or platinum-iridium, which are twisted to form a wire rope, drawn through successive dies to generate a radiopaque wire or cable of reduced diameter, and preferably annealed." *Id.* at column 3, lines 10-20. Alternatively, Avellanet discloses wires comprising multiple nickel-titanium strands that are wound around a single central high density strand of gold, silver, or platinum iridium wire. *Id.* at lines 20-25 and 55-65. As a result, "a cable which exhibits flexibility substantially equal to or greater than a single strand nickel-titanium alloy wire of the same cross section" is obtained. *Id.* at column 4, lines 10-17 (emphasis added). Like Nagy, Avellanet is completely silent with respect to the addition of ternary elements to the NiTi strands of the guidewire.

Thus, one of ordinary skill in the art, having knowledge of the impact of ternary elements on the flexibility of NiTi wires, would not have been motivated, much less with a reasonable expectation of success, by the disclosure of Avellanet to form the wires of

a stent from the ternary guidewire alloy disclosed by Nagy. For these additional reasons, the rejection over the combination of Nagy and Avellanet is improper and should be withdrawn.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of pending claims 29-77.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: January 9, 2006
for
October 5, 2005

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